

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

PLEXXIKON INC.,

Plaintiff,

v.

NOVARTIS PHARMACEUTICALS
CORPORATION,

Defendant.

Case No. [17-cv-04405-HSG](#)

**ORDER DENYING MOTION TO
EXCLUDE EXPERT TESTIMONY OF
TED SWEENEY**

Re: Dkt. No. 206

Pending before the Court is Defendant Novartis Pharmaceuticals Corporation's motion to exclude the testimony of Plaintiff Plexxikon Inc.'s expert Ted Sweeney. Dkt. No. 206. The Court heard argument on this motion. *See* Dkt. No. 341. As detailed below, the Court **DENIES** the motion.

I. BACKGROUND

This is a patent infringement case related to Plaintiff's patents for kinase inhibitors. Plaintiff accuses Defendant's melanoma drug Tafenlar, which Defendant acquired from GlaxoSmithKline ("GSK") in 2015. Tafenlar works by inhibiting B-Raf, a type of kinase. As relevant to this motion, Tafenlar is approved both as a monotherapy and as a combination therapy with Mekinist, an MEK (another type of kinase) inhibitor. *See* Dkt. No. 234 at 2; *see also* Dkt. No. 206 at 1, & n.1–2. Plaintiff's product, Zelboraf, is also approved as a combination therapy with an MEK inhibitor, Cotellic. *Id.* The Tafenlar-Mekinist combination, however, was approved by the FDA in January 2014, approximately two years before the Zelboraf-Cotellic combination was approved by the FDA in November 2015. *Id.*; *see also* Dkt. No. 206-2, Ex. 1 ("Sweeney Report") at ¶¶ 19–20, 23–31, 39–47.

Defendant challenges the testimony of Plaintiff's clinical expert, Ted Sweeney. *See* Dkt.

No. 206. In his expert report, Mr. Sweeney describes the “first-mover advantage,” in which a new pharmaceutical product retains market share because it is the first of its kind on the market, rather than because of any inherent advantage in the product compared to later competitors. *See* Sweeney Report at ¶¶ 7–12. He concludes that Defendant benefits from a first-mover advantage in the B-Raf/MEK market based on the Tafenlar–Mekinist combination, which is largely responsible for the combination’s high market share compared to the Zelboraf-Cotellic combination (rather than the relative price, side-effect profile, or efficacy of the combinations). *See id.* at ¶¶ 54–96, 102–04. In other words, Mr. Sweeney posits that the Tafenlar-Mekinist combination has been successful—more successful than the Zelboraf-Cotellic combination—because it was first. Defendant seeks to exclude Mr. Sweeney’s expert testimony. Dkt. No. 206.

II. LEGAL STANDARD

Federal Rule of Evidence 702 allows a qualified expert to testify “in the form of an opinion or otherwise” where:

(a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. Expert testimony is admissible under Rule 702 if it is both relevant and reliable. *See Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993). “[R]elevance means that the evidence will assist the trier of fact to understand or determine a fact in issue.” *Cooper v. Brown*, 510 F.3d 870, 942 (9th Cir. 2007); *see also Primiano v. Cook*, 598 F.3d 558, 564 (9th Cir. 2010) (“The requirement that the opinion testimony assist the trier of fact goes primarily to relevance.”) (quotation omitted).¹ Under the reliability requirement, the expert testimony must “ha[ve] a reliable basis in the knowledge and experience of the relevant discipline.” *Primiano*, 598 F.3d at 565. To ensure reliability, the Court “assess[es] the [expert’s]

¹ Whether to admit expert testimony is evaluated “under the law of the regional circuit,” so in this case, under the law of the Ninth Circuit. *See Micro Chem., Inc. v. Lextron, Inc.*, 317 F.3d 1387, 1391 (Fed. Cir. 2003).

reasoning or methodology, using as appropriate such criteria as testability, publication in peer reviewed literature, and general acceptance.” *Id.* at 564.

III. DISCUSSION

Defendant contends that (1) Mr. Sweeney lacks the required expertise to testify as an expert about the first-mover advantage; (2) his opinions lack an appropriate factual basis; and (3) his methodology is not sound. *See* Dkt. No. 206.

A. Qualifications

As an initial matter, Defendant argues that Mr. Sweeney lacks the qualifications to testify as an expert in pharmaceutical economics because he does not hold a degree in economics and has never before been qualified as an expert in a case. *See* Dkt. No. 206 at 5–6. The Court is not persuaded.

The Ninth Circuit has explained that Rule 702 “contemplates a *broad conception* of expert qualifications.” *Hangarter v. Provident Life & Acc. Ins. Co.*, 373 F.3d 998, 1018 (9th Cir. 2004) (emphasis in original). Rule 702 explicitly anticipates that an expert may be qualified through his “knowledge, skill, experience, training, *or* education.” *See* Fed. R. Civ. P. 702 (emphasis added). Consequently, “an expert need not be officially credentialed in the specific matter under dispute.” *See Massok v. Keller Indus., Inc.*, 147 F. App’x 651, 656 (9th Cir. 2005) (citing *United States v. Garcia*, 7 F.3d 885, 889–90 (9th Cir. 1993)).² That Mr. Sweeney has not testified as an expert before is similarly inapposite. As the Ninth Circuit has noted, an expert’s “normal workplace” is “not the courtroom or the lawyer’s office.” *See Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995) (*Daubert II*).

Here, Mr. Sweeney’s expert report details his extensive experience. He is the President and Managing Partner of Jupiter Life Science Consulting. *See* Sweeney Report at ¶¶ 1–2; *see also id.* at App’x A. For approximately 20 years, he has worked as a consultant in the biopharmaceutical industry, analyzing pricing, demand, and access for biopharmaceutical products. *See id.* He has worked “to address licensing, development, launch, post-marketing

² As an unpublished Ninth Circuit decision, *Massok v. Keller* is not precedent, but may be considered for its persuasive value. *See* Fed. R. App. P. 32.1; CTA9 Rule 36-3.

1 portfolio, and policy needs” for biopharmaceutical companies around the world. *See id.* at ¶ 2.
2 Mr. Sweeney states that as such, he has contributed to the commercial success of 75% of the top
3 performing drugs in the United States biopharmaceutical market. *See id.* In short, Mr. Sweeney
4 appears to have decades of experience analyzing commercial pricing strategy in the
5 biopharmaceutical industry.

6 Defendant attempts to minimize the relevance of this experience, concluding that “Mr.
7 Sweeney’s experience in pharmaceutical consulting, much of which is concerned with the
8 management of consulting companies, [does not] qualify him as an expert in pharmaceutical
9 economics.” *See* Dkt. No. 206 at 6. But Defendant offers no support for this assertion, and it
10 appears to be contradicted by Mr. Sweeney’s expert report and CV. Although Mr. Sweeney may
11 have experience managing the consulting firms at which he worked over the years, he also
12 described the substantive experience that he has gained from working for biopharmaceutical
13 clients while at these companies.

14 Rather than address this experience directly, Defendant simply cites to a single out-of-
15 circuit case, *Hidden Oaks v. City of Austin*, 138 F.3d 1036, 1050 (5th Cir. 1998). *See* Dkt. No.
16 206 at 6. This case is inapposite. In *Hidden Oaks*, the district court found that the plaintiff’s
17 proffered damages expert lacked the necessary qualifications to testify as an expert in appraising
18 property. *Id.* The proffered expert testified that as part of his job, he often evaluated the worth of
19 various properties to determine if his employer should make an offer and at what price. *Id.* But
20 on cross-examination, the expert stated that he was not a licensed appraiser, was not a licensed real
21 estate broker, had no formal schooling regarding appraisal methods, and was unable to respond to
22 the defense attorney’s questions about “standard appraisal theory.” *Id.* The Fifth Circuit did not
23 consider the expert’s appraisal experience, but instead concluded that the district court acted
24 within its discretion when it excluded his testimony based on the totality of the circumstances. *Id.*
25 Here, in contrast, there is no evidence in the record that Mr. Sweeney was unable to understand or
26 explain the fundamentals of pharmaceutical market economics generally, or the first-mover
27 advantage more specifically.

28 Defendant suggests that Plaintiff has not identified any experience that would qualify Mr.

Sweeney to testify as an expert about market dynamics for “BRAF inhibitors” or “melanoma therapeutics” in particular. *See* Dkt. No. 206 at 1; *see also* Dkt. No. 246 at 1–2. Defendant thus defines the relevant expertise narrowly, but fails to explain why the first-mover advantage may differ for B-Raf inhibitors or melanoma treatments as compared to other pharmaceutical products. Defendant will have the opportunity to probe Mr. Sweeney’s expertise at trial. But at this stage, the Court finds that Plaintiff has met its burden of establishing Mr. Sweeney’s qualifications.

B. Factual Basis

Next, Defendant contends that Mr. Sweeney’s opinions are not founded on sufficient facts or data. *See* Dkt. No. 206 at 6–7 (citing Fed. R. Evid. 702(b)). In his expert report, Mr. Sweeney opined that the price difference between Tafenlar and Zelboraf does not account for their difference in market share. *See* Sweeney Report at ¶¶ 71–85. Defendant argues that Mr. Sweeney did not rely on any GSK documents or testimony in reaching this conclusion, and therefore proffers speculation about GSK’s pricing decisions in the guise of expert opinion. Dkt. No. 206 at 6–7.

In his expert report and deposition, however, Mr. Sweeney discussed in detail the bases for his opinions, including price and sales data for the four drug products. He explained that “price discounting” is rare in the oncology market because the market is less price-sensitive. *See* Sweeney Report at ¶¶ 75–76. He thus concluded that GSK’s initial pricing strategy for Tafenlar—offering it at a significant discount relative to Zelboraf—“was more likely” done in anticipation of its expected use in combination with Mekinist. *Id.* at ¶ 78. He further stated that GSK could compensate for the Tafenlar price discount by pricing Mekinist higher, and the combined price of the Tafenlar-Mekinist combination still signaled to the market “GSK’s belief that the combination regimen was clinically superior to Zelboraf monotherapy.” *See id.* at ¶¶ 78–79. Mr. Sweeney also explained that GSK (and later Defendant) increased the price of Tafenlar annually, noting that “[i]nsurers rarely re-review and change coverage policies unless price increases stand out as excessive and inordinate with other products” and “Novartis likely recognized that because it had established a strong foothold in the market over the prior 2.5 years without competition, these price increases would not affect prescriber behavior” *See id.* at ¶¶ 80–84; *see also* Dkt. No.

206-3, Ex. 2 (“Sweeney Depo.”) at 243–25:21. That Mr. Sweeney relied on market dynamics and his industry experience rather than GSK’s own representations or internal documents does not render his opinions baseless.

To the extent that Defendant believes Mr. Sweeney’s conclusions about GSK’s pricing decisions—and the reason for Tafenlar’s market share—are incorrect, Defendant may cross-examine Mr. Sweeney at trial and highlight that he did not rely on GSK documents in opining on its pricing strategy. But the Court declines Defendant’s invitation to step in as factfinder and determine which facts are most relevant or reliable. “*Daubert* makes the district court a gatekeeper, not a fact finder.” *See United States v. Sandoval-Mendoza*, 472 F.3d 645, 654 (9th Cir. 2006).

C. Methodology

Lastly, Defendant argues that Mr. Sweeney does not identify or reliably follow any accepted methodology in concluding that Defendant benefits from a first-mover advantage. *See* Dkt. No. 206 at 7–10 (citing Fed. R. Evid. 702(c)–(d)). Although Defendant does not explain what methodology Mr. Sweeney should have followed, it points out that Mr. Sweeney did not quantify the magnitude or duration of any first-mover advantage. *See id.* at 7–9, & n.7. But neither Rule 702 nor *Daubert* precludes qualitative analyses. To the contrary, the Supreme Court has cautioned that the *Daubert* inquiry is intended to be flexible, and that when evaluating specialized or technical expert opinion testimony, “the relevant reliability concerns may focus upon personal knowledge or experience.” *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999). As noted above, Plaintiff has adequately explained that Mr. Sweeney has relevant knowledge and experience to testify about pricing dynamics in the pharmaceutical industry. Mr. Sweeney’s reliance on this experience—whether or not he quantified the benefit of Defendant’s alleged first-mover advantage—does not render his opinions unreliable.

Defendant also cites facts that Mr. Sweeney may not have considered in his analysis. *See, e.g.,* Dkt. No. 246 at 3. For example, Defendant asserts that Mr. Sweeney did not consider the marketing of the drugs or combination therapies. *See Sweeney Depo.* at 16:24–18:4, 20:23–22:25. But in his deposition, Mr. Sweeney noted that the companies responsible for the Tafenlar-Mekinist

1 combination and the Zelboraf-Cotellic combination are all “considered highly competent
2 marketing companies,” and he found it salient that the Tafinlar-Mekinist combination “was
3 available and then subsequently promoted without competition” for years. *See id.* at 17:14–19,
4 40:1–10. Defendant cites other facts that Mr. Sweeney failed to consider, such as the number of
5 patients who are prescribed a B-Raf/MEK combination therapy, the number of physicians in the
6 treating physician population, and the physicians’ individual prescribing practices. *See* Dkt. No.
7 206 at 8–10. Yet Defendant does not explain the relevance of these facts to the existence of a
8 first-mover advantage, and none appear to render Mr. Sweeney’s opinion so unreliable as to
9 require exclusion. Both in his report and deposition, Mr. Sweeney detailed the facts that he
10 considered and how he applied his experience to these facts in evaluating whether Defendant
11 benefits from a first-mover advantage. *See generally* Sweeney Report. He also explored the
12 possibility that other factors influenced Defendant’s market share outside of the first-mover
13 advantage. *See id.* at ¶¶ 54–96.


14 To the extent Defendant disagrees with Mr. Sweeney’s approach or conclusions, it will
15 have ample opportunity to cross-examine him at trial and present its own contrary evidence. *See*
16 *Daubert*, 509 U.S. at 596 (“Vigorous cross-examination, presentation of contrary evidence, and
17 careful instruction on the burden of proof are the traditional and appropriate means of attacking
18 shaky but admissible evidence.”). The jury ultimately will have to decide how persuasive it finds
19 Mr. Sweeney’s testimony.

20 **IV. CONCLUSION**

21 Accordingly, the Court **DENIES** the motion.

22 **IT IS SO ORDERED.**

23 Dated: 6/8/2021

24 
25 HAYWOOD S. GILLIAM, JR.
26 United States District Judge
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